STATEMENT OF WORK

Title: **National Environmental Laboratory Accreditation Conference Standards Gap Analysis for the USEPA Regional Laboratories**

Estimated Period of Performance: 9 months from data of award

I. BACKGROUND

The U.S. EPA Regional Laboratory Branch Chiefs recognize the critical need to ensure the integrity of analytical services provided by the regional laboratory network. As part of the ongoing process of ensuring data integrity, the regional laboratories will seek accreditation under the National Environmental Laboratory Accreditation Conference (NELAC) standards.

II. SCOPE OF WORK

The purpose of this Statement of Work is to conduct gap analyses at nine[1] U.S. EPA regional laboratories to determine what actions the laboratories must take to be accredited under the standards adopted by the National Environmental Laboratory Accreditation Conference. A separate gap analysis shall be performed on each laboratory. The results of each gap analysis shall be summarized in a written report and provided to the project officer (PO).

The basis for the gap analysis shall be the NELAC Standards approved May 2001 (Effective 2003). The standards are available on the NELAC web site at http://www.epa.gov/ttn/nelac. The scope of each gap analysis is to be as follows:

Laboratory	Location	Scope of Gap Analysis #
Region 1	11 Technology Drive N. Chelmsford, Massachusetts	DW, NPW, SCM, AIR
Region 2	2890 Woodbridge Ave. Edison, New Jersey	DW, NPM, SCM
Region 3	701 Mapes Road Ft. Meade, Maryland	DW, NPW, SCM
Region 4	980 College Station Road Athens, Georgia	DW, NPW, SCM

[1] The Region 7 laboratory is already an accredited laboratory and will not participate.

Laboratory	Location	Scope of Gap Analysis #
Region 5	536 South Clark Street Chicago, Illinois	NPW, SCM
Region 6	10625 Fallstone Road Houston, Texas	DW, SCM
Region 8	8TMS-L 16194 W 45th Drive Denver, Colorado	DW
Region 9	1337 South 46th Street, Bldg 201 Richmond, California	DW, NPW, SCM
Region 10	7411 Beach Drive East Port Orchard, Washington	DW

DW - Drinking Water
NPW - Non-Potable Water
SCM - Solids and Chemical Materials
BIO - Biological Tissues
AIR- Air Samples

The gap analysis shall include a review of the laboratory Quality System and a review of selected matrix-technology/methods. Matrix-technology/methods for which the laboratory seeks gap analysis will be identified in the documentation submitted to the contractor in Task 2.

The contractor shall use their expertise to determine 10 matrix-technology/methods to review from the list of those provided by the laboratory. Selection of the 10 should cover as broad an array of matrix-technology/method as possible both in terms of matrix and technology/method. The method specific gap analysis shall seek to identify areas where the laboratory may have weaknesses relative to NELAC method requirements as contained in Chapter 5 and appendices D.1 - 4 of the NELAC Quality Systems Checklist.

Task 1: General Project Planning and Management

Under this task the contractor shall perform several general project management functions in support of this project.

1.1 Initial Meeting with the project officer (PO). The contractor shall meet with the PO within 5 days of contract award to review the project tasks and to discuss issues related to the conduct of the work. This meeting shall be considered part of the background review and shall be the basis for the contractor's work plan.

1.2 Work Plan. Within 10 working days of the contract award, the contractor shall submit a work plan to the PO. The work plan shall include the contractors approach to completing the SOW tasks and shall provide the names and brief resumes of proposed

contract personnel. The PO will provide comments on the plan with in 5 working days of receipt. The contractor shall incorporate the changes necessary to respond to the comments made by the PO and submit a revised plan with in 5 working days of receipt of the PO's comments.

1.3 Meetings with the Project Officer and Technical Contacts. The contractor's project manager shall be prepared to meet with the PO and technical contacts via teleconference throughout the period of performance. The PO will provide the agenda for the teleconference.

1.4 Monthly Status Reports. The contractor shall prepare (1-2 page) monthly status reports to be submitted electronically to the PO. Status reports shall include progress to date on each of the nine gap assessments highlighting any issues which would potentially impact the work plan. The status of the current month's activities is due by the last calendar day of each month.

Task 1 Deliverables

- Draft Work Plan - Due 10 working days after award
- Final Work Plan - Due 5 working days after EPA comments
- Monthly Status Reports - Due the last calendar day of each month.

Task 2: Gap Analysis Planning

The contractor shall provide each laboratory with available dates* for their respective on-site assessments from which the laboratory can select. The laboratory will provide the selected date to the contractor within 10 working days. Once the laboratory selects the date of the on-site, the laboratory will provide the contractor with the following documents within 30 calendar days.

1. Laboratory Quality Manual (however named)
2. Standard Operating Procedures applicable to the laboratory's scope.
3. Proficiency test results applicable to the laboratory's scope
4. List of personnel with responsibilities related to the laboratory's scope.
5. Copies of previous assessment reports
6. A list of "Technology/Methods" within each "Matrix" for which the laboratory seeks Gap analysis

* Priority shall be given to scheduling Regions 9, 3 and 1 early in the performance period because these laboratories have already begun the process of applying for NELAC accreditation and anticipate assessment audits in late 2003.

Task 2 Deliverables

- Letter of introduction with available dates to each laboratory - Due 10 working days after work plan approval.
- Letter confirming the date of audit for each laboratory - Due 30 calendar days prior to on-site visit.

Task 3: Information Collection and Review

The contractor shall review laboratory records for accuracy, completeness and the use of proper methodology . Task 2 lists the records requiring review during Task 3. The assessor must document the required elements of the records review on. Based on the laboratory's submitted documentation, the contractor shall develop a written plan, no more than 2 pages double-sided, for each of the nine on-site assessments. The plan shall include:

1. the scheduled date(s) of on-site assessment
2. the composition of the contractor's assessment team
3. the 10 matrix-technology/methods to be included in the review
4. the records to be reviewed on-site
5. general time schedule of contractor's activities/interviews during on-site

The assessment plan shall be submitted to the laboratory director and to the PO within 30 calendar days of the on-site.

Task 3 Deliverables

- Assessment Plan for each laboratory - Due within 30 calendar day of the on-site.

Task 4 On-Site Gap Analysis

The contractor shall conduct an entrance briefing with laboratory management and staff (designated by the laboratory director) to review the assessment plan and to finalize the schedule. The areas to be evaluated during the on-site gap analysis of the laboratory include

1. Organization and Management
2. Quality System - Establishment, Assessments, Essential Quality Controls and Data Verification
3. Personnel
4. Physical Facilities - Accommodation and Environment
5. Equipment and Reference Material
6. Measurement Traceability and Calibration
7. Sample Handling, Sample Acceptance Policy and Sample Receipt
8. Records
9. Laboratory Report Format and Contents
10. Subcontracting of Analytical Samples
11. Outside Support Services and Supplies
12. Complaints

13. Test Methods and Standard Operating Procedures (10 selected methods, see Scope of Work)

The gap analysis shall evaluate the laboratory against the standards detailed in Chapter 5, Quality Systems, Chapter 2, Proficiency Testing and Chapter 4, Accreditation Process of the NELAC Standards and the appropriate methods references. NELAC assessment checklists shall be used (available on the NELAC web site at http://www.epa.gov/ttn/nelac).

Task 4 Deliverables

- Verbal debriefing of the laboratory staff at the closure of the onsite evaluation.

Task 5: Gap Analysis Report

The final Gap Analysis Report shall be written to contain a description of each identified gap referencing each to a specific requirement in the NELAC Standards by specific chapter, section and paragraph number.

5.1 Reports Analysis reports shall be generated in a narrative format. The checklists used by the assessor(s) during the gap analysis shall be an attachment to the final report. The assessor shall specify the records, documents, equipment, procedures, or staff evaluated and the observations that contributed the assessors determination of a "Yes" or "No" response for each checklist item.

The Gap Analysis report shall contain:

1. Identification of the laboratory
2. Date of analysis
3. Identification and affiliation of each analysis team member
4. Identification of participants in the analysis process
5. Statement of the objective of the gap analysis
6. Summary
7. Analysis observations and identified gaps
8. Comments and recommendations

5.2 Delivery Reports shall be drafted within 30 working days after the onsite visit. Each Laboratory Director is to be allowed 15 working days to review and comment on the draft. The contractor shall then have an additional 15 working days to finalize the report. Final reports shall be delivered to the PO for distribution. Results of the gap analysis shall be considered business confidential information and shall not be disclosed except as noted here or as required by a court of law..

Task 5 Deliverables

- Draft Gap Analysis Report - Due 30 working days after onsite visit
- Final Gap Analysis Report - Due 15 working days after EPA comments

III Special Skills Requirements

The contractor must be able to document experience conducting laboratory gap analyses, demonstrate expertise in the NELAC standards, and maintain registration as a lead auditor. Because this scope of work includes reviewing drinking water technologies and methods at EPA laboratories, the contractor must have training and experience assessing laboratories performing EPA Organic, Inorganic, and Microbiology Drinking Water methods and EPA Organic and Inorganic Wastewater Methods. The above requirements shall be documented in the contractor's work plan (Task 1.2)

Criteria for Award

(Based on Chapter 16 Contracts Management Manual, 1900 CHG 16, 10/22/97
and Section B.6 of Contract 68-C-99-246 & Contract 68-C-99-247)

The issuance of the Statement of Work will be to the contractor with the highest composite score of technical and cost components.

The contractor shall prepare a proposal that includes a full description of the technical approach that shall be used in addressing the requirements of this SOW. In addition the contractor shall indicate proposed staff, their function and expertise, and their proposed commitment of hours for this Statement of Work. Proposed personnel will be evaluated on the basis of their relevancy of their qualifications and experience with respect to this specific TO. A general schedule with proposed deliverables (interim and final) shall be included and evaluated on the basis of necessity to complete the Statement of Work in a timely fashion, and need to devote adequate staff time to the project. For the cost proposal, a table showing costs by professional level and expected Other than Direct Costs (including travel, printing & shipping etc.) is needed. The contractor's response to this proposed TO should not exceed 15 pages double-sided.

Contractor selection will be based on the evaluation of qualifications and expertise in the following areas:

- Participation in the NELAC Basic Training Course (NELAC section 3.2.3.1).
- Conducted at least 4 NELAC assessments or NELAC Gap Analyses.
- The contractor's lead assessor must have specific experience assessing laboratories performing EPA Organic, Inorganic, and Microbiology Drinking Water methods and EPA Organic and Inorganic Wastewater Methods. Documentation of specific training and experience should be provided as part of the bid submission.
- The contractor's lead assessor must be a registered lead auditor (e.g., RAB ISO QMS auditor).

Evaluation Criteria:

A. Technical component: 90 points

i. technical and innovative approach to the SOW	5 points
ii. proposed staffing, level of expertise, experience	70 points
iii. proposed method for effectively reporting progress	5 points
iv. proposed method to ensure work quality	5 points
v. delivery schedule and milestones	5 points

B. Cost component: 5 points

i. cost reasonableness, level of effort, ODC	5 points

C. Past performance on similar contracts: 5 points

TOTAL **100 points**

Each sub-component will be scored on a scale of 5:

5/5	Superior features predominate with no weaknesses
4/5	Very good with some superior features only
3/5	Good with no superior features and some weaknesses
2/5	Adequate but weaknesses predominate and need correction
1/5	Critical weaknesses and deficiencies that must be corrected
0/5	Fails to address the SOW